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# Design considerations for tools supporting multi-centre clinical trials

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## Introduction

Miscarriage, defined as the loss of pregnancy before the fetus reaches viability, is the most common complication of pregnancy. As many as 15-25% of pregnancies end in miscarriage<sup>1</sup> but, due to the limited data collected, the actual miscarriage rate is unknown. Currently, couples with recurrent miscarriages are routinely screened for various endocrine, immune, anatomical and genetic risk factors<sup>2</sup>. However, the ability of these tests to stratify women in terms of pregnancy outcome and assign appropriate treatment has not been rigorously tested due to lack of prospective data.

## Methods

The Tommy's National Centre for Miscarriage Research aims to collate information from multiple observational and interventional studies, miscarriage clinics, and maternity databases, across the UK, into one system (Tommy's Net). It is intended to connect to sites' clinical IT systems and consolidate information, map data elements between sources, resolve differences in procedures and capture study-specific information for analysis at a national level. Tommy's Net is based on the CURE framework<sup>3</sup>, a modular system for collecting research data in secondary care settings. The framework includes methods for the standardized, flexible capture and storage of data. When developing the system, three network configurations were assessed, by listing the advantages of each and prioritising features in terms of their support for data entry from multiple sites, ease of installation and monitoring, ease of integration with existing systems, their security and ability to collate data and support further development: **Distributed** – sites store data collected locally, using their own schema and preferred data collection tools. **Federated** – sites install a local copy of the system and transfer data to a central repository. **Centralized** – sites enter data directly into a central system.

## Results and Conclusion

The Centralized option was chosen as it provides a central database, makes maintenance and recovery of the system simpler and, using a web-based system, allows authorised users to connect from any participating site. One of the participating Trusts was also chosen to host the system, making use of the UK's secure national broadband network, the Health and Social Care Network (<https://digital.nhs.uk/health-social-care-network>), and the existing capability of UK trusts to transfer electronic data internally, using HL7 v2 as the communication standard. By exposing a HL7 FHIR interface and connecting to the host trust's integration engine, the Tommy's Net system will be able to request data electronically from all participating Trust EHRs in a scalable manner as long as the trust IT teams allow access from the host trust. Other integration mechanisms will be considered based on the standards adopted by the Trusts.

The Tommy's Net system is currently running at UHCW and is being used by research midwives to enter miscarriage data. Other participating sites will start using Tommy's Net in the coming months and approval has been obtained to integrate Tommy's Net with Trust EHRs to share demographic and other information for patients registered with the Trust, avoiding redundant data entry by allowing data already collected by the Trusts to be imported. Tommy's Net has been developed for use by miscarriage services within the UK to enable population-based epidemiological studies and facilitate large cohort studies. The design of the system promotes interoperability with existing Trust systems to allow researchers to use information already collected, and collect pregnancy outcomes, so that participating Trusts can benchmark clinic success rates and identify high risk groups of patients for future research.

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